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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,180	12/10/2001	William W. Zuo	27300/03	3508

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EXAMINER
MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,180	ZUO ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT OF PRELIMINARY AMENDMENT AND THE STATUS OF THE CLAIMS

1. The preliminary amendment filed 10/22/02 is acknowledged, entered and considered. Claims 1-54 arte now present for examination.

OBJECTION TO THE SPECIFICATION, CLAIMS AND ABSTRACT

2. The specification, claims and abstract are objected in the recitation "U:\G&S\Clients\Fannin\03\PATAPP.wpd" and "Express Mail No. EL 872 048 512US" at the end corner of each page of the specification, claims and abstract. Deletion of the above file locator from the disclosure of the specification, claims and abstract would obviate this objection. Also, on page 27, line 5, in the recitation "platinu". It is believed to be typographical error. Appropriate correction is required.

OBJECTIONS TO THE ABSTRACT LANGUAGE

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. Applicant uses legal phraseology such as "said" on lines 9 and 12 of the abstract. It is suggested that the use of the legal phraseology "said" should be avoided. Also, on line 11, in the recitation "saiduch". Thus, appropriate correction is required. See MPEP 608.01(b).

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 and dependent claims 2-7 thereof and independent claim 20 and dependent claims 21-27 thereof are directed to a therapeutic compound claims, wherein a compound is known to be defined as one component. However, claims 1-7 and 20-27 comprise several components, which make the claims composition claims. It is not clear how claims 1-7 and 20-27 differ from composition claims 28-34 and 36-43, respectively since they have identical components claimed. As such, there would appear to be no difference in scope between claims 1-7, 20-27 and 28-34, 36-43, respectively. Hence, both sets of claims appear to claim the same subject matter (See e.g., MPEP 706.03 [k]).

Claim 46 is indefinite in the recitation "A method for treating a patient afflicted with a condition.....". It is not clear what is meant by "a patient afflicted with a condition" because the "condition" is not defined in the claims or in the specification, and as such, one can not determine he metes and bounds of the claimed condition.

CLAIMS REJECTION-35 U.S.C. § 103(a)

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bichon (U.S. Patent No. 4,675,381) taken with Myers et al., (U.S. Patent No. 5,087,616) or Ghadiri (U.S. Patent No. 5,410,020) or Sharma (U.S. Patent No. 6,027,711).

Bichon teaches the process of making and using of biodegradable acyloxymethyl polyaspartate and polyglutamate as drug carrier in an encapsulated or incorporated state in the matrix of the polymer. The polymer may also be in the form of a copolymer with other polyaminoacids as recited in formula II, also, all other amino acids are, in principle, possible for polymer formulation. It is equally possible to have amino acids of the L or D series with the aim of obtaining polymers of which the rate of degradation has been altered. Thus, clearly motivating one of ordinary skill in the art to use any amino acid of interest in combination with polyaspartate and/or polyglutamate polymers to obtain a polypeptide drug carrier (See e.g., abstract, cols 2, lines 58 to col. 3, lines 28 and claim 5) as directed to claims 1, 3-4, 9-10, 12-13, 20, 22-23, 30-31 and 38-39. With

respect to the total weight of the carrier moiety, the reference states that, for example, if the copolymer were a copolymer of polyglutamate and of leucine, the relative molar preparation of the two constituents as a function of the relative rate of degradation would be selected, at the place in question, from polyglutamate and polyleucine. In general, the ratio z/y can vary by 1 to 30, but these limits may be exceeded if necessary. Thus, the reference's teachings overlap with ranges of the total weight of the carrier moiety as claimed in the instant invention (See e.g., col. 3, lines 29-43) as directed to claims 1, 8, 11, 14-17, 28 and 36. The reference on col. 4, lines 13-17, states that the polymers of the invention may comprise elements of L or D configuration or racemic mixtures or even polymers where one of the configurations is dominant, and as such, meets the limitation of claim18. Also, on col. 6, lines 29 to 44, the prior art states that the polymers can be used to store drugs in various ways, for example, the polymers can be used to produce microcapsules containing a drug, wherein the polymeric membrane comprises an aqueous or oily solution in which the drug is in suspension or in solution. It is also possible to manufacture microspheres, i.e., solid particles or balls containing the drug in a dispersed state or in the form of solid solution in the polymer matrix. It is also possible to produce microporous products called microsponges. In general, it is possible using the present polymers to apply all the methods of manufacturing delayed release drugs, i.e., drugs having the property of releasing (salting out) the drug in a prolonged manner as the carrier degrades, and as such meets the limitations of claims 44 and 45. Further, the reference teaches administering by injection (parent rally) the composition for treating a patient afflicted with a condition having inflammatory infection (See e.g., col. 10, lines 7-10) as directed to claims 46, 48-49 and 54. Thus, the primary reference of Bichon teaches the use of polyglutamate and/or polyaspartate polymers as drug carriers, wherein the drug is encapsulated or incorporated in the matrix of the polymers.

The reference of Bichon differs from claims 1-54 in failing to use specific molecular weight as recited in the claims and the employment of metal complex with the polymer. However, the reference of Myers et al., teach the use of a biodegradable polymeric carrier (polyglutamic acid) to which one or more cytotoxic molecules, such as daunomycin is conjugated (See e.g., col. 3, lines 35-54). The reference on col. 6, lines 17-25 also teaches, the combination of glutamic acid and aspartic acid for the synthesis of polymer. On col. 7, lines 47 to 66 and claims 1 and 10, the prior art discloses various molecular weights of the polypeptide polymers, the preferred molecular weight of the total conjugate is in the range of 10,000 to 100,000 D, and less than 50,000 is especially preferred. Thus, the ranges of the molecular weight claimed overlaps with the prior art range disclosed, and as such, meets the limitations of claims 2, 19, 21, 27, 29, 35, 37, 43, 47 and 53.

Further, the reference of Ghadiri teaches method for preparing metallopeptide having stabilized secondary structure by incorporating two amino acid residues in the polypeptide chain that provide side chains to form ligands with a metal ion. Thus, incorporation of selected amino acid residues into an amino acid residue sequence that defines a secondary structure provides metal ligand contact sites necessary to form a metal binding site on the polypeptide, thereby producing a metallopeptide having stabilized secondary structure. Thus, the reference contemplates compositions containing a metallopeptide (See e.g., col. 2, lines 3-13 and col. 5, lines 65-66). On col. 8, lines 4-13, the reference states that the nature of the bonding between metal and ligand is usually characterized as ionic but it may also be of the covalent type. Also, on col. 13, lines 27-51, the reference states that a metal cation suitable for use as a component of a metallopeptide of this invention can be any metal cation capable of complexing with the polypeptide present in the metallopeptide composition, so long as the complexing occurs with the ligand provided by the two coordinating amino acid

residues that define the metal binding site of the metallopeptide. Typical metal cations include zinc, cadmium, manganese, iron, platinum, rhodium, cobalt, etc. Thus, the reference concludes by stating many different metal cations can be selected as suitable for use as metal cation in a metallopeptide composition, and as such, meets the limitations of claims 5-7, 19, 24-27, 32-35, 40-43 and 50-53. Similarly, the reference of Sharma on cols. 10-11 teaches metallo-constructs, which include a plurality of amino acids, with substantially all the valences of the metal ion satisfied upon complexation of the metal ion to nitrogen, sulfur or oxygen atoms in the amino acids available for complexing with the available valences of the metal ion. The metal ion complexed to the peptide may be an ionic form of the elements iron, cobalt, manganese, indium, rhenium, platinum, etc. Further, on col. 22, lines 34 to 43, the reference teaches methods of designing peptide-metal ion complexes by selecting a peptide chain which encompasses the groups that individually are necessary for providing a coordination site for complexation with metal ion. Also, on col. 31, lines 22-26, the reference states that the complexation of the metal ions to the peptide, and especially to the metal ion-complexing backbone of the peptide, is achieved by mixing appropriate amounts of the peptide with the metal ion. Thus, showing the formation of complexes with metal ion, and as such meets the limitations of claims 5-7, 19, 24-27, 32-35, 40-43 and 50-53.

Therefore, the combined teachings of the prior art makes obvious the use of polypeptide transition-metal complexes containing a polypeptide carrier moiety comprising glutamic acid and a group of amino acids such as alanine, asparagines, glutamine, glycine and any combinations thereof, wherein the drug is a therapeutic metal such as iron, platinum, gadolinium, rhenium, manganese, cobalt, indium, gallium, or rhodium, and method for making said complexes/compositions and use of such complexes/compositions for treating a patient afflicted with a condition, absence of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDANCE

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Mohamed/AAM
September 29, 2003